AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

Serial Number: 10/633,402

Filing Date: August 1, 2003

Title: IMPROVED TREATMENT OF CANCER WITH GLUTAMINE

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IN THE CLAIMS

Please amend the claims as follows.

1-5. (Canceled)

6. (Currently Amended) A method of protecting non-mucosal tissue against damage from

radiation therapy, the method comprising:

orally administering to a mammalian subject afflicted with breast cancer and treated with

radiation therapy a composition comprising a therapeutically effective amount of glutamine or a

pharmaceutically acceptable salt thereof, and carbohydrate in an amount effective to increase the

absorption of glutamine by the subject, wherein the composition protects the non-mucosal tissue

the breast tissue or associated upper body tissue against damage from the radiation therapy, so

that the subject can be treated with a higher dose of radiation and/or treated with radiation for a

longer time.

7-9. (Canceled)

10. (Original) The method of claim 9 wherein the composition prevents increased breast

density or lessens the severity of increased breast density.

11. (Previously Presented) The method of claim 6 wherein the composition prevents edema

or lessens the severity of edema.

12. (Original) The method of claim 11 wherein the edema is of breast tissue.

13. (Currently Amended) The method of claim 6 wherein the non-mucosal tissue is skin.

14. (Currently Amended) The method of claim 6 wherein the composition protects the

appearance of the non-mucosal tissue.

15-43. (Canceled)

- 44. (Previously Presented) The method of claim 6, wherein the amount of glutamine administered is at least 0.5 mg per day per kg body mass of the subject.
- 45. (Original) The method of claim 44 wherein the amount of glutamine administered is 0.2 g to 3.0 g per day per kg body mass of the subject.
- 46. (Previously Presented) The method of claim 6, wherein the amount of glutamine administered to the subject is less than 0.5 g per kg per day.
- 47. (Previously Presented) The method of claim 6, wherein the amount of glutamine administered to the subject is less than 0.1 g per kg per day.
- 48. (Previously Presented) The method of claim 6, wherein the carbohydrate comprises one or more monosaccharides or disaccharides.
- 49. (Previously Presented) The method of claim 6, wherein the carbohydrate comprises a sugar alcohol.
- 50. (Previously Presented) The method of claim 6, wherein the weight ratio of total carbohydrate to glutamine in the composition is 0.5:1 to 50:1.
- 51. (Previously Presented) The method of claim 6, wherein the weight ratio of total carbohydrate to glutamine is at least 4:1 in an aqueous solution, either after preparation with an aqueous solvent or after delivery in an aqueous environment of the mammalian subject.
- 52. (Previously Presented) The method of claim 6, wherein the composition comprises no more than 5 naturally occurring amino acids other than glutamine.

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53. (Original) The method of claim 52 wherein the composition comprises no naturally occurring amino acids other than glutamine.

- 54. (Canceled)
- 55. (Previously Presented) The method of claim 6, wherein the mammalian subject is a human.
- 56. (Previously Presented) The method of claim 6, wherein the composition is administered after or while administering radiation therapy to the subject.
- 57-58. (Canceled)